No. 14-7955

IN THE

Supreme Court of the United States

RICHARD E. GLOSSIP, ET AL.,
Petitioners,

v.

KEVIN J. GROSS, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Tenth Circuit

BRIEF FOR PETITIONERS

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QUESTIONS PRESENTED

1. Is it constitutionally permissible for a state to carry out an execution using a three-drug protocol where:

(a) there is a well-established scientific consensus that the first drug has no pain relieving properties and cannot reliably produce deep, coma-like unconsciousness, and

(b) it is undisputed that there is a substantial, constitutionally unacceptable risk of pain and suffering from the administration of the second and third drugs when a prisoner is conscious?

2. Does the *Baze*-plurality stay standard apply when states are not using a protocol substantially similar to the one that this Court considered in *Baze*?

3. Must a prisoner establish the availability of an alternative drug formula even if the state's lethal-injection protocol, as properly administered, will violate the Eighth Amendment?

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 24.1(b), the following list identifies all of the parties before the United States Court of Appeals for the Tenth Circuit.

Charles F. Warner, Richard E. Glossip, John M. Grant, and Benjamin R. Cole, by and through his next friend Robert S. Jackson, were appellants below. These appellants collectively petitioned this Court for a writ of certiorari. Petitioner Charles F. Warner was executed by the State of Oklahoma on January 15, 2015, after the decision below and before this Court granted the petition. Appellants Glossip, Grant, and Cole are petitioners here.

Kevin J. Gross, Michael W. Roach, Steve Burrage, Gene Haynes, Frank "Frazier" Henke, Linda K. Neal, Earnest D. Ware, Robert C. Patton, and Anita K. Trammell were appellees below and are respondents here. Respondents are all employees or agents of the Oklahoma Department of Corrections. All respondents are sued in their official capacities only.

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OPINIONS BELOW

The order of the United States District Court for the Western District of Oklahoma denying relief is reported at 2014 WL 7671680 (W.D. Okla. Dec. 22, 2014), J.A. vol. I 41-42 [hereinafter J.A.].

The opinion of the United States Court of Appeals for the Tenth Circuit denying relief is reported at 776 F.3d 721 (10th Cir. 2015), J.A. 111-39.

This Court's grant of a stay of petitioners' executions pending disposition of this case or Oklahoma's selection of a constitutionally permissible lethal-injection protocol is reported at 2015 WL 341655 (2015), J.A. 140.

JURISDICTION

The court of appeals issued its decision affirming the district court's denial of a preliminary injunction on January 12, 2015. The petition for certiorari was filed on January 13, 2015. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Eighth Amendment to the United States Constitution provides in relevant part that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. Const. amend. VIII.

Title 42, section 1983, of the United States Code states that "[e]very person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction

thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress . . . ." 42 U.S.C. § 1983.

INTRODUCTION

Oklahoma intends to execute petitioners by injecting them with large amounts of a paralytic drug and potassium chloride. The paralytic drug produces a chemical entombment, paralyzing and eventually suffocating the person. Potassium chloride feels like liquid fire as it courses through the veins; it eventually stops the heart. Throughout this process, the paralytic drug ensures that observers see no evidence of suffering, because the prisoner will be completely paralyzed.

It is constitutionally intolerable to use these drugs to execute any prisoner still capable of sensing pain. These drugs cause not merely death, but also agonizing pain and suffering. Such a method of execution violates the Eighth Amendment's prohibition against cruel and unusual punishment. The Framers placed off limits such means of execution as burning a prisoner. From the perspective of causing intolerable pain and suffering, injecting a prisoner with liquid fire is just as unconstitutional as lighting him afire.

The administration of painful drugs is constitutional only if the prisoner is first placed in a deep, comalike state of unconsciousness, comparable to the anesthesia that precedes an otherwise painful surgery. For a quarter century, lethal injections using painful drugs have begun with the administration of barbiturates—either sodium thiopental or pentobarbital—which reliably induce and maintain a comalike state that renders a person insensate to pain. When

properly administered, barbiturates eliminate the risk that a prisoner will feel pain from the administration of other lethal drugs.

The State of Oklahoma now intends to use the anti-anxiety drug midazolam (sold under the trade name Versed) rather than a barbiturate, as the sole drug to anesthetize prisoners. Midazolam, however, is not approved or used as a standalone anesthetic during painful surgeries, because it is inherently incapable of reliably inducing and maintaining deep, comalike unconsciousness. The substitution of midazolam for barbiturates creates an objectively intolerable risk that prisoners will experience excruciating pain and suffering during their executions.

The Tenth Circuit upheld Oklahoma's use of midazolam based on a misunderstanding of this Court's decision in *Baze* v. *Rees*, 553 U.S. 35 (2008), and of petitioners' claim. Unlike in *Baze*, petitioners are not seeking procedures to avoid human error in carrying out an otherwise constitutional method of lethal injection. Petitioners instead are challenging a method of lethal injection that, even if carried out as written, will be cruel and unusual. That method violates the Eighth Amendment.

STATEMENT OF THE CASE

I. BACKGROUND

1. In the lethal-injection formula approved in *Baze*, "[t]he first drug, sodium thiopental (also known as Pentothol), is a fast-acting barbiturate sedative that induces a deep, comalike unconsciousness when given in the amounts used for lethal injection." *Baze*, 553 U.S. at 44. "The second drug, pancuronium bromide (also known as Pavulon), is a paralytic agent that inhibits all muscular-skeletal movements and,

by paralyzing the diaphragm, stops respiration." *Id.* "Potassium chloride, the third drug, interferes with the electrical signals that stimulate the contractions of the heart, inducing cardiac arrest." *Id.*

The Court recognized that the second and third drugs in this lethal-injection formula would cause objectively intolerable pain and suffering in a person who is not in a comalike state. The Court thus acknowledged that, "failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride." *Id.* at 53. Consequently, whether the injection of the paralytic[1] and potassium chloride as a method of execution passes constitutional scrutiny depends on whether the state adopts a reliable means for first rendering the prisoner deeply unconscious, and thus "ensures that the prisoner does not experience any pain associated with the paralysis and cardiac arrest caused by the second and third drugs." *Id.* at 44. Because sodium thiopental does reliably produce a "deep, comalike unconsciousness," *id.*, and because Kentucky's procedures included "safeguards" for properly administering the formula, the Court concluded that there were not "objectively intolerable" risks of maladministration. *Id.* at 62. Ap-

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[1] This brief uses "paralytic" to refer to pancuronium bromide, vecuronium bromide, and rocuronium bromide. All agree that these drugs are functionally equivalent insofar as each will produce paralysis and agonizing asphyxiation in an aware individual, who will be unable to communicate his terror, pain, and suffering. It also was undisputed that potassium chloride will produce burning and intense pain as it circulates through the body. Answer to Amended Complaint at ¶ 50, *Warner* v. *Gross*, No. 5:14-cv-665 (W.D. Okla. Nov. 14, 2014), ECF No. 96; *see* J.A. 341; *see also* J.A. 218-19.

plying these standards, this Court upheld Kentucky's three-drug protocol.

2. In the context of lethal injection, there is no medical dispute that sodium thiopental, if effectively administered, will reliably produce "deep, comalike unconsciousness." *Baze*, 553 U.S. at 44. All parties in *Baze* conceded that sodium thiopental had that property. *Id.* The Court's recognition of sodium thiopental's capabilities is also supported by its accepted medical use "as the sole anesthetic agent for brief (15 minute) procedures." DailyMed, *Thiopental Sodium*, Label Archives (Feb. 7, 2011), https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=48745;[2] see also J.A. 296-97. As the anesthesiologist who testified below explained, a large dose of sodium thiopental will cause a "barbiturate coma." J.A. 207.[3] A patient in such a coma will not sense the pain and suffering caused by the paralytic or potassium chloride, or the pain of an invasive surgical procedure. See, *e.g.*, J.A. 206-07, 226.

At the time of *Baze*, sodium thiopental was manufactured domestically by Hospira, Inc. In 2010,

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[2] The product label is the "most objective and complete information that we have about a drug and its legal use within the United States." J.A. 259. Any "indications and usage[s]" endorsed by the label "means that the manufacturer . . . has submitted clinical trials that have been reviewed by FDA scientists that show that the drug actually does what the manufacturer says that it will do." J.A. 261; J.A. 259; *see Mut. Pharm. Co.* v. *Bartlett*, 133 S. Ct. 2466, 2471 (2013).

[3] A coma is a state of profound unconsciousness from which one cannot be roused, even by powerful, noxious stimulation. *Stedman's Medical Dictionary* 414 (28th ed. 2006); *Dorland's Illustrated Medical Dictionary* 358 (28th ed. 1994).

Hospira developed regulatory and supply difficulties.[4] Hospira then intended to transfer its thiopental-manufacturing business to a new facility in Italy. See Alan M. Wolf, *Hospira Halts Rocky Mount Production of Death Penalty Drug*, N. Observer (Raleigh, N.C.), Jan. 21, 2011. Owing to this shortage, several states imported sodium thiopental from unregistered foreign sources. See *Cook* v. *FDA*, 733 F.3d 1, 4 (D.C. Cir. 2013). The Court of Appeals for the District of Columbia later held that those imports violated federal law. *Id.* at 10-11. Subsequently, in 2011, Hospira decided to exit the U.S. market entirely, explaining that the company was not confident that it could comply with Italy's laws relating to capital punishment. See Press Release, Hospira, Inc., Hospira Statement Regarding Pentothal™ (sodium thiopental) Market Exit (Jan. 21, 2011), *available at* http://phx.corporateir.net/phoenix.zhtml?c=175550&p=irol-newsArticle&ID=1518610&highlight.

Thereafter, several states, including Oklahoma, chose to replace sodium thiopental with another barbiturate, pentobarbital.[5] Pentobarbital, like sodium

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[4] *See, e.g.*, Warning Letter from John R. Gridley, Dir. Atl. Dist., FDA, to Christopher B. Begley, CEO, Hospira Inc. (Apr. 12, 2010), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm208691.htm (describing manufacturing violations at Hospira's facility at Rocky Mount, North Carolina); Am. Soc'y of Health-System Pharmacists, *Thiopental Injection*, Discontinued Drug Bulletins (Jan. 21, 2011), http://www.ashp.org/menu/DrugShortages/DrugsNoLongerAvailable/Bulletin.aspx?id=563 (noting issues with raw-materials supplier).

[5] Several states abandoned the three-drug approach in favor of a one-drug method using an overdose of a single barbiturate—essentially the method the petitioners in *Baze* had proposed. *See, e.g.*, *Towery* v. *Brewer*, 672 F.3d 650, 657 (9th Cir. 2012) (Arizona); *Pavatt* v. *Jones*, 627 F.3d 1336, 1337 n.1 (10th Cir.

thiopental and other barbiturates, is "capable of producing . . [a] deep coma." DailyMed, *Label: Nembutal Sodium*, http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5c380ab0-4386-48b6-80ab-ca594b23bc74 (last update May 2012). It is also commonly used for non-human animal euthanasia. See *Baze*, 553 U.S. at 58. Courts upheld Oklahoma's (and other states') use of pentobarbital as a replacement for sodium thiopental because "the use of pentobarbital to induce a barbiturate coma, which . . . is a common use of pentobarbital, takes the patient to a state of unconsciousness beyond a normal clinical level of anesthesia." *Pavatt*, 627 F.3d 1337, 1339 (10th Cir. 2010).[6] From December 2010 to January 2014, Oklahoma carried out seventeen executions using pentobarbital as the first drug in its three-drug protocol. J.A. 153; Justin Juozapavicius, *Oklahoma Will Not Review Protocol After Recent Executions*, NewsOK.com, Jan. 28, 2014, http://newsok.com/oklahoma-will-not-review-protocol-after-recent-executions/article/3927866/?page=1.

Meanwhile, in July 2011, the manufacturer of pentobarbital, Lundbeck, placed distribution controls on

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2010) (Washington); *Cooey* v. *Strickland*, 589 F.3d 210, 215 (6th Cir. 2009) (Ohio).

[6] *See DeYoung* v. *Owens*, 646 F.3d 1319 (11th Cir. 2011) (upholding as constitutional Georgia's use of pentobarbital as the first drug in three-drug protocol); *Powell* v. *Thomas*, 641 F.3d 1255 (11th Cir. 2011) (same regarding Alabama); *Beaty* v. *Brewer*, 649 F.3d 1071 (9th Cir. 2011) (same regarding Arizona); *Jackson* v. *Danberg*, 656 F.3d 157 (3rd Cir. 2011) (same regarding Delaware); *Valle* v. *Singer*, 655 F.3d 1223 (11th Cir. 2011) (same regarding Florida); *Rhoades* v. *Reinke*, 671 F.3d 856, 860 n.1 (9th Cir. 2011) (same regarding Idaho); *Beaty* v. *Brewer*, 791 F. Supp. 2d 678, 683 (D. Ariz. 2011) ("[P]entobarbital has been used either singularly or as a substitute for sodium thiopental in executions in Mississippi, Ohio, South Carolina, and Texas.").

the drug to prevent what it deemed the "misuse" of its products in executions.[7] Lundbeck's corporate decision gradually reduced the supply of pentobarbital to prisons, and states began seeking pentobarbital from other sources.[8] Some states considered different drug combinations.[9] And still others, including Oklahoma, Florida, and Alabama, retained a three-drug protocol, but chose midazolam as the first drug. See J.A. 51; *Muhammad* v. *State*, 132 So.3d 176, 188 (Fla. 2013) (noting Florida switched to midazolam in three-drug protocol in October 2013); *Arthur* v. *Thomas*,

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[7] *See* Press Release, Lundbeck, Lundbeck Overhauls Pentobarbital Distribution Program to Restrict Misuse (July 1, 2011), *available at* http://investor.lundbeck.com/releasedetail.cfm?ReleaseID=605775.

[8] *See, e.g.*, *Wellons* v. *Commissioner, Ga. Dep't of Corr.*, 754 F.3d 1260, 1262 (11th Cir.) (per curiam) (suggesting that Georgia is using compounded pentobarbital), *cert. denied sub nom. Wellons* v. *Owens*, 134 S. Ct. 2838 (2014); *In re Lombardi*, 741 F.3d 888, 891 (8th Cir.) (Missouri using compounded pentobarbital), *cert. denied sub nom. Zink* v. *Lombardi*, 134 S. Ct. 1790 (2014); *Chester* v. *Wetzel*, No. 1:08-cv-1261, 2012 WL 5439054, at *7 (M.D. Pa. Nov. 6, 2012) (Pennsylvania using compounded pentobarbital); *Whitaker* v. *Livingston*, 732 F.3d 465, 468 (5th Cir.) (per curiam) (Texas using compounded pentobarbital), *cert. denied sub nom. Yowell* v. *Livingston*, 134 S. Ct. 417 (2013).

[9] In January 2014, Ohio used midazolam in combination with hydromorphone to carry out an execution. *See In re Ohio Execution Protocol Litig.*, 994 F. Supp. 2d 906, 913 (S.D. Ohio 2014). The execution was not without incident. *See infra* at p. 20-21. In July 2014, Arizona used the same combination of drugs as Ohio, and it resulted in a nearly two-hour execution. *See* Order, *Wood* v. *Ryan*, No. 2:14-cv-01447-NVW (D. Ariz. July 24, 2014), ECF No. 34. Executions are currently stayed in both Ohio and Arizona. *See* Press Release, Ohio Dep't of Rehabilitation & Corr., Execution Dates Revised (Jan. 30, 2015), *available at* http://www.drc.ohio.gov/Public/press/press437.htm; Order, *Wood*, No. 2:14-cv-01447-NVW (D. Ariz. Nov. 24, 2014), ECF No. 68.

No. 2:11-cv-438-WKW, 2015 WL 224738, at *1 n.1 (M.D. Ala. Jan. 15, 2015) (noting Alabama switched to midazolam in September 2014).

3. Oklahoma's current lethal-injection protocol, effective September 30, 2014, was developed by the Oklahoma Department of Corrections. Pls.' Ex. 68, *Warner*, No. 5:14-cv-665 (OSP Execution Procedures OSP-040301 (Sept. 30, 2014))[10] Under the protocol, there are four different drug formulas[11]—two of which use midazolam—and the Director of the Department of Corrections has the sole discretion to choose which one is to be used. See *id.* at 36-38.

On March 17, 2014, days before the scheduled execution of Clayton Lockett and Charles Warner, Pls.' Ex. 13, *Warner*, No. 5:14-cv-665 (Order Setting Execution Date, *Warner* v. *State*, Okla. Crim. App., Case No. D-2003-829 (Jan. 23, 2014)); Pls.' Ex. 14, *Warner*, No. 5:14-cv-665 (Order Setting Execution Date, *Warner* v. *State*, Okla. Crim. App., Case No. D-2000-1330); the Oklahoma Attorney General announced that his usual source of pentobarbital "fell through," and he had not found it elsewhere. Pls.' Ex. 15 at 8, *Warner*, No. 5:14-cv-665 (Supp. Br. of Appellee State of Oklahoma, *Lockett* v. *State*, Okla. Crim. App., Case Nos. D-2000-1330 & D-2003-829 (Mar. 17, 2014)).[12]

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[10] Under Oklahoma law, lethal injection is the default method of execution. *See* 22 Okla. Stat. Ann. § 1014(A) (2011).

[11] The options are: a one-drug method using pentobarbital; a one-drug method using sodium thiopental; a two-drug method combining midazolam and hydromorphone; or a three-drug method with midazolam followed by a paralytic and then potassium chloride.

[12] Oklahoma's usual pentobarbital source is not clear, but an investigation uncovered emails between Oklahoma officials joking in 2011 that Oklahoma would reveal to Texas officials how

Rather than seeking to postpone the scheduled executions, the Attorney General set out to find alternative drugs that were immediately available on the open market. Pls.' Ex. 15 at 9, *Warner*, No. 5:14-cv-665; see also J.A. 148; J.A. vol. II 4-6.

On March 21, only four days after announcing difficulty in obtaining pentobarbital,[13] the respondents chose midazolam as a replacement for pentobarbital in the three-drug protocol, retaining the paralytic and potassium chloride.[14] J.A. 145; J.A. vol. II 29; J.A. vol. II 31. Oklahoma's selection of midazolam was grounded in expedience, rather than science.

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to deal with the sodium thiopental shortage in return for 50-yard-line tickets for "Team Pentobarbital" to the Oklahoma-Texas football game. *See* Katie Fretland, *Records Show Oklahoma Officials Wanted Perks for Helping Texas in Search for Scarce Lethal Injections*, Colo. Indep. (Mar. 18, 2014), http://www.coloradoindependent.com/146553/oklahoma-scrambles-to-find-lethal-injections-for-two-imminent-executions.

[13] As the State was unable to find a replacement before Lockett's scheduled execution, the executions of both Lockett and Warner were eventually reset for April 29. Pls.' Ex. 16 at 3, *Warner*, No. 5:14-cv-665 (Order Vacating & Resetting Execution Dates, *Lockett* v. *State*, Okla. Crim. App. Case Nos. D-2000-1330 & D-2003-829 (Mar. 18, 2014)); Exec. Order No. 2014-08, Governor of Oklahoma (Apr. 22, 2014), *available at* https://www.sos.ok.gov/documents/executive/939.pdf).

[14] The State attempted to buy compounded midazolam and compounded pancuronium bromide before ultimately purchasing manufactured midazolam and vecuronium bromide. *See* Pls.' Ex. 1, *Warner*, No. 5:14-cv-665 (Letter to Madeline Cohen & O. Dean Sanderford from Assistant Attorney General John Hadden (Apr. 11, 2014)); Pls.' Ex. 8, *Warner*, No. 5:14-cv-665 (Letter to Madeline Cohen & O. Dean Sanderford from Assistant Attorney General John Hadden (Apr. 4, 2014)); Pls.' Ex. 17, *Warner*, No. 5:14-cv-665 (Letter to John Hadden from Madeline Cohen & O. Dean Sanderford (Apr. 10, 2014)).

Based upon anecdotes from other states and internet postings, including "Wiki leaks or whatever it is," lawyers for the State concluded—incorrectly—that "midazolam had the same properties as pentobarbital as far as sedation goes." J.A. vol. II 7; J.A. 145; J.A. 149. No State officials responsible for selecting midazolam consulted with any experts, doctors, or scientists. J.A. vol. II 4; Tr. of Prelim. Inj. Hr'g at 300, *Warner* v. *Gross*, No. 5:14-cv-665 (W.D. Okla. Dec. 17-19, 2014) [hereinafter Tr.]; J.A. 157. Rather, respondents claimed that midazolam would survive constitutional scrutiny "because a court in Florida found it constitutional." Tr. 508. The State moved with haste to ensure that then-scheduled executions would go forward, acknowledging that "[i]f either pentobarbital or sodium thiopental were available, Director Patton[, one of the respondents here,] would have selected them rather than the midazolam protocols." J.A. 79; J.A. 147; J.A. 164.

But Florida's use of midazolam as the first drug in a three-drug protocol does not establish that midazolam is effective at maintaining deep unconsciousness. By preventing movement, the paralytic masks a prisoner's suffering if he returns to consciousness from the pain of the paralytic and potassium chloride. See J.A. 333 (testimony of respondents' expert). Thus, midazolam's shortcomings—and a prisoner's suffering—may be discernible only in an execution where the administration of the paralytic was interrupted. See *Warner* v. *Gross*, 135 S. Ct. 824, 826-27 (2015) (Sotomayor, J., dissenting) (discussing problems with Oklahoma's execution of Clayton Lockett).

4. Midazolam belongs to a class of drugs called benzodiazepines. J.A. 286; J.A. 171; J.A. 204-05; J.A. 260-61; J.A. 341; Tr. 661. Benzodiazepines include drugs such as Valium, Ativan, and Xanax; midazolam

is the shortest acting of the class. J.A. 171. Benzodiazepines, including midazolam, are used for their anti-anxiety, anti-seizure, sedative, and muscle-relaxant properties. They are prescribed to treat anxiety disorders and insomnia, to reduce anxiety before general anesthesia, and for conscious sedation for minor outpatient procedures. J.A. 241, J.A. 287-88; J.A. 171. Midazolam is approved for use "for preoperative sedation/anxiolysis/amnesia," J.A. 287; see also J.A. 203, and is mainly used prior to medical procedures to calm a patient. J.A. 171; J.A. 203. Most importantly, midazolam is not approved for—and, in fact, is not used as—the sole anesthetic during a painful procedure. Tr. 145; J.A. 206.

To explain the properties of midazolam and its use in medical settings and in Oklahoma's execution procedures, petitioners presented expert testimony from David Lubarsky, M.D., a practicing anesthesiologist and Chairman of the Department of Anesthesiology at the University of Miami, Miller School of Medicine, J.A. 200; Eric D. Katz, M.D., a practicing emergency medicine physician and Chairman of the Department of Emergency Medicine at the University of Arizona College of Medicine, J.A. 337-38; and Larry Sasich, Pharm. D., a consulting pharmacist with ten years of experience as a research analyst, and sixteen years of experience as a clinical professor, J.A. 257-58. Respondents chose to present testimony from Roswell L. Evans, Pharm. D., a dean at the school of pharmacy at Auburn University whose scholarship in the past twenty years addresses pharmacy education, teaching, and economics. J.A. 305-06; Defs.' Ex. 34 at 6718-22, *Warner*, No. 5:14-cv-665 (Dec. 17-19, 2014) (Curriculum Vitae of R. Lee Evans). Evans's scholarship in pharmacology is limited, and he has not published a clinical study of drug effects since approximately

1997. Defs.' Ex. 34 at 6718-22, *Warner*, No. 5:14-cv-665.

a. All experts agreed that midazolam is neither approved by FDA for use as, nor used as, the sole drug to maintain general anesthesia during a painful procedure. Tr. 145; J.A. 203 ("[S]urgeons can] do a full operation with a barbiturate. You cannot do that with midazolam."); J.A. 223 ("[Midazolam] would never be used and has never been used as the sole anesthetic to give anesthesia during a surgery. Not ever."); J.A. 327; see also J.A. 76; J.A. 204. The experts also agreed that midazolam has no analgesic (or pain-relieving) qualities. J.A. 204-05; J.A. 261; J.A. 341; J.A. 310-11; Tr. 661; see also J.A. 76. Accordingly, respondents' expert testified that if physicians wanted to use midazolam "as the sole anesthetic agent in a painful procedure," he would "advise them not to do that." J.A. 332-33.

Midazolam's inability to serve reliably as the sole anesthetic for a painful procedure was established in clinical trials, where patients who were "given midazolam in doses sufficient to produce unconsciousness d[id] not tolerate the noxious stimuli of surgery." Tr. 143; see also J.A. 219 (petitioners' expert explaining that midazolam "was not approved by the FDA as a sole anesthetic because after the use of fairly large doses that were sufficient to reach the ceiling effect and produce induction of unconsciousness, the patients responded to the surgery"). The studies show that although midazolam can cause unconsciousness and unresponsiveness to minor stimuli, a person rendered unconscious by midazolam is not in a comalike state, and can be "jolted into consciousness" by the infliction of pain. J.A. 230-31; see J.G. Reves et al., *Midazolam: Pharmacology and Uses, Anesthesiology* 62:310 at 318 (1985) ("Midazolam cannot be used

alone, however, to maintain adequate anesthesia. . . .").[15]

b. Petitioners' experts also explained why midazolam cannot reliably serve as general anesthesia, and why barbiturates can. Barbiturates and benzodiazepines are different classes of drugs that work "via different mechanisms" and "in different strength." J.A. 172, 206, 207. Barbiturates do not have a "ceiling effect," and can quiet all brain activity and cause a coma in a way that midazolam cannot. J.A. 206-07; Robert K. Stoelting & Simon C. Hillier, *Pharmacology & Physiology in Anesthetic Practice* 141 (4th ed. 2005) ("Midazolam, in contrast to barbiturates and propofol, is unable to produce an isoelectric EEG [a coma].").

Midazolam facilitates the binding of gamma-aminobutyric acid (GABA) to GABA receptors in the brain. J.A. 172, 206-07. GABA is a naturally occurring substance within the body that serves to inhibit brain activity. J.A. 232; J.A. 206. GABA inhibits the

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[15] The experts further agreed that clinical doses of midazolam can cause a "paradoxical reaction," where a person experiences "agitation, combativeness, and anxiety as a result of the administration of the drug." J.A. 210; *see also* J.A. 263; Tr. 669. The FDA-approved product labeling warns of paradoxical reactions, *see* J.A. 290; J.A. 263-64; Tr. 349, which are more likely to occur in people—like petitioners—with "behaviors such as aggression, impulsivity, substance abuse, and suffering from other psychiatric disorders or psychological disturbances." Tr. 116; *see* Pls.' Ex. 81 at 2-3, *Warner*, No. 5:14-cv-665 (Aff. of Donna Schwartz-Watts, *Grant* v. *Workman*, N.D. Okla., Case No. CIV-05-167-TCK); Pls.' Ex. 82 at 4, 24-31, *Warner*, No. 5:14-cv-665 (Indep. Psychiatric Consultation re Benjamin Cole – Report conducted by Raphael Morris, M.D., in *Cole* v. *Workman*, Case No. CIV-08-328-CVE); Pls.' Ex. 83 at 4-5, *Warner*, No. 5:14-cv-665 (Decl. of Ruben C. Gur, Ph.D. in *Cole* v. *Workman*, Case No. CIV-08-328-C); Pls.' Ex. 84, *Warner*, No. 5:14-cv-665 122 (Okla. Dep't of Corr. Mental Health Record, Richard Glossip).

flow of electrical impulses through the neurons in the brain. When GABA binds to a receptor on a neuron, it makes it "much harder for a neuron in the brain to send along an electrical impulse." J.A. 207. The effect of GABA is useful to healthy brain functioning, for example preventing seizures. But at an extreme, when enough neurons in the brain stop firing, a person will no longer feel sensation or process thoughts. J.A. 206.

Barbiturates, including pentobarbital and sodium thiopental, also facilitate the activity of GABA to inhibit neurons. J.A. 207; J.A. 172; J.A. 232. But barbiturates have an additional, direct effect on GABA receptors that midazolam does not have. Barbiturates bind directly to receptors, mimicking the action of GABA. Stoelting & Hillier, *supra*, at 128. Thus, even if all the naturally occurring GABA has been bound, barbiturates will bind to additional GABA receptors and inhibit more and more neurons from firing. A large amount of barbiturates will silence brain activity and create a coma. J.A. 206.

Unlike barbiturates, midazolam does not mimic GABA, bind to receptors, and stop neurons from firing electrical impulses on its own; midazolam needs GABA to affect brain activity. J.A. 172. Thus, midazolam's effect is effectively capped by the limited amount of GABA in the brain. J.A. 172; J.A. 206, 208-09. Once all GABA has been bound, increasing the dose of midazolam does not suppress additional brain activity. J.A. 205-06. This is midazolam's "ceiling effect," a fundamental and unavoidable pharmacological property shared by all benzodiazepines, which

clinical studies in rats and in humans have demonstrated. J.A. 265; J.A. 209.[16]

In other words, although "people normally assume that, well, if you give twice as much of the drug you would get twice that effect[,] [t]hat's not the case with midazolam." J.A. 205-06.[17] Instead, unlike barbiturates, midazolam's effect is capped ultimately by the body's own production of GABA. J.A. 205-06. Because barbiturates can mimic GABA and bind to GABA receptors, their administration has no comparable ceiling effect. J.A. 208-09; J.A. 226.

Given midazolam's ceiling effect, and its poor performance as the sole anesthesia in clinical trials, midazolam cannot reliably provide the deep, comalike state necessary to avoid responsiveness to pain. See Tr. 145 (Dr. Lubarsky's opinion is "based on what we

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[16] *See* Stoelting & Hillier, *supra*, at 141 ("[B]enzodiazepines have a built-in ceiling effect that prevents them from exceeding the physiologic maximum of GABA inhibition. The low toxicity of the benzodiazepines and their corresponding clinical safety is attributed to this limitation of their effect on GABAergic neurotransmission.").

[17] The fact that midazolam has a ceiling effect was acknowledged by all experts and established below. J.A. 206; Tr. 343; Tr. 664. Although respondents' distinguished this effect as something that occurs only on "the spinal cord" and not "in the brain," J.A. 78; Tr. 664; J.A. 311-12, that statement misapprehends basic physiology—midazolam's ceiling effect occurs because of the body's finite supply of GABA, which is not limited to the spinal cord. When GABA is exhausted, midazolam has no further effect. *See* Stoelting & Hillier, *supra*, at 141; Steven C. Curry et al., *Neurotransmitters*, *Goldfrank's Toxicology Emergencies* 155 (6th ed. 1998) ("In general, GABA inhibition predominates in the brain. In the spinal cord, through mono- and polysynaptic reflex pathways, GABA mediates a number of physiologically minor peripheral effects outside the CNS (*e.g.*, vasodilation, bladder relaxation).").

know about mechanisms of action, how it works, where it binds, that it has a ceiling effect, that it has been studied in both humans and rats and deemed insufficient for surgical anesthesia in any dose form by the FDA").

c. Notwithstanding the above evidence, respondent's expert opined that 500 milligrams of midazolam would induce and maintain comalike unconsciousness in a person during the period between its administration and death. J.A. 327-28; Tr. 666. He based his conclusion on two linked conjectures.

First, respondents' expert presumed that a "toxic" dose of midazolam would cause a sustained coma before it caused death. Tr. 661. He admitted, however, that "there are no studies that have been done and probably could be done" to corroborate the supposition that a "toxic reaction" to midazolam would cause a sustained coma before causing death. J.A. 327. He could cite no data, studies, or reports establishing that a toxic administration of midazolam ever has caused—much less reliably would cause—a sustained coma rendering a person insensate to pain. *Id.* He instead testified that he simply "extrapolat[ed]" from his understanding of how midazolam could cause deaths to assume that, at some point before death, a coma would occur. *Id.*

Second, respondents' expert opined that 500 milligrams of midazolam would be a sufficiently "toxic" dose to cause death within thirty minutes and, in some non-specified but associated way, a coma. *Id.*; J.A. 332. Dean Evans arrived at this opinion through unidentified sources[18] and mathematical error. To de-

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[18] Respondents' expert stated that there have been 80 reports of deaths "from the use of midazolam . as of 2009." J.A. 294; J.A. 309. He lacked any authority for the proposition and was

termine a "toxic" dose, Evans consulted "drugs.com"—which has a disclaimer that it is "not intended for medical advice, diagnosis or treatment," J.A. 275-76; J.A. 259; J.A. 303; Tr. 364-65—but was unable to point to data regarding a toxic dose on that site. J.A. 329-31.[19] He also cited a Material Safety Data Sheet ("MSDS") about midazolam. J.A. 294. The Occupational Safety and Health Administration ("OSHA") requires chemical manufacturers to post an MSDS to alert workers and downstream users about the potential hazards of handling a given chemical, see 29 C.F.R. § 1910.1200(g), and the MSDS warns that its data should not be relied upon "regarding its correctness." Defs.' Ex. 34 at 6560, *Warner*, No. 5:14-cv-665 (Dean Evans's Expert Report). This MSDS does not purport to define a clinically lethal dose, see Tr. 656, but only the amount of midazolam reported to be "toxic." Defs.' Ex. 34 at 6558, *Warner*, No. 5:14-cv-665 (reporting "TD_{LO} man, intravenous = 71 mg/kg"). It does not state whether or how often "toxic" doses resulted in death, or whether any dose created sustained comalike unconsciousness or pain suppression.

Moreover, in interpreting the MSDS, Evans admitted that he committed a basic mathematical error and underestimated the "toxic" dose for an average adult by a factor of one thousand. J.A. 329. Instead of the lowest "toxic" dose occurring at 0.071 mg/kg, as Evans originally opined, the number in the MSDS is

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"unclear" about the circumstances. *Id.* Dr. Lubarsky acknowledged "serious adverse events" with midazolam, but explained they occurred with "90-year-olds with congestive heart failure" and "rarely if ever" with "healthy individuals." J.A. 217.

[19] Petitioners' expert testified he would "not accept a work product from a student" if "drugs.com was used as the reference source." J.A. 259. *See* Tr. 337-38; J.A. 282-83.

71 mg/kg. J.A. 329. For a 70-kilogram adult, a "toxic" dose according to the MSDS thus would be 4,970 milligrams (that is, 71 mg times 70 kg), or ten times *more* than the 500-milligram dose Evans opined would cause coma and death.[20]

5. Oklahoma used midazolam for the first time in its execution of Clayton Lockett, on April 29, 2014. The State administered 100 milligrams of midazolam, and Lockett was declared unconscious seven minutes later. J.A. 53; Tr. 214-15; J.A. vol. II 46-48; Pls.' Ex. 93 at 4401, *Warner*, No. 5:14-cv-665. Lockett was then administered the paralytic and most of the potassium chloride. J.A. 53; Tr. 170. During the administration of the second and third drugs, however, Lockett awoke. J.A. 215-16, 345, 339. He began to writhe against the gurney, buck his head, and said "this shit is f[---]ing with my mind," "something is wrong," and "the drugs aren't working." J.A. 53; J.A. 350-51, 355-56; Tr. 181; Tr. 205; Tr. 219-20; Tr. 494. The viewing blinds that allowed witnesses to see into the execution chamber were then lowered. J.A. 56-57.[21] Twenty-four minutes later, Lockett died. J.A. 56.

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[20] Evans's unsupported assertion that 500 milligrams of midazolam reliably would be lethal and coma-causing formed the basis for his other opinions. Evans agreed that the ceiling effect exists, but testified that, "whatever the ceiling effect of midazolam may be with respect to anesthesia," it would be overcome by "a 500 milligram dose [which would] effectively paralyze the brain." J.A. 78. Evans also agreed that paradoxical reactions can occur, including after sedation, Tr. 670; *see also* J.A. 264; J.A. 244-45, but again opined—again without support—that a 500-milligram dose would prevent it. J.A. 315; Tr. 669.

[21] Witnesses were not fully able to observe Lockett's pain before the blinds were lowered, however, because Oklahoma had taped Lockett's hands into fixed positions and concealed his body under sheets, masking signs of distress. Pls.' Ex. 39 at

A state-commissioned report later concluded that a catheter failure caused the lethal drugs, at some point, to infiltrate Lockett's tissue instead of directly entering his bloodstream. J.A. 398; J.A. 51-52; Tr. 561-62. As a result, the second drug failed to effectively paralyze Lockett, allowing witnesses to see his return to consciousness and suffering, J.A. 53; J.A. 218 ("[The paralytic provides a] false sense of security and prevents people from seeing whether or not that surgical plane of anesthesia is still maintained.").

One hundred milligrams of midazolam did not place Lockett in deep, comalike unconsciousness before the paralytic and potassium chloride were administered.[22] Having been jolted into consciousness, Lockett "was surely experiencing all of the mental pain that is inevitable in the execution process as well as serious physical discomfort if not serious physical pain." J.A. 54. Moreover, midazolam provided no pain relief, Tr. 61-66; Tr. 352-55, as it is not pharmacologically capable of doing so. J.A. 204-05; J.A. 260-61; J.A. 310; Tr. 661. Lockett was "awake and struggling against the effects and the pain of the other drugs." J.A. 214.

Midazolam's inability to cause a deep comalike unconsciousness also was seen during executions in Ohio and Arizona. Each State has executed a prisoner using a mixture of midazolam and

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1619, *Warner*, No. 5:14-cv-665 (DPS Interviews of Paramedic (May 28, 2014; July 31, 2014)); Tr. 50.

[22] The IV failure would not have significantly impacted midazolam's effectiveness, because midazolam—unlike the paralytic—has a rapid absorption rate, even if not administered intravenously. J.A. 173; Tr. 116; J.A. 246-47; Tr. 352.

hydromorphone.[23] In January 2014, Ohio used 10 milligrams of midazolam and 40 milligrams of hydromorphone to execute Dennis McGuire, who gasped for nearly ten minutes before his death. See Alan Johnson, *Execution; State Will Increase Lethal Dosages*, Columbus Dispatch, Apr. 29, 2014, at 1B. In July 2014, Arizona used far more of each drug—750 milligrams of midazolam and 750 milligrams of hydromorphone—to execute Joseph Wood, and yet he gasped for nearly two hours before dying. See Fernanda Santos, *Executed Arizona Inmate Got 15 Times Standard Dose, Lawyers Say*, N.Y. Times, Aug. 2, 2014, at A11. Dr. Lubarsky testified below that the execution of Wood amounted to "unintentional experimental proof that large doses of midazolam do not necessarily kill you, [nor do they] guarantee unconsciousness, and that the administration of additional doses do not cause further depression of consciousness[.] [Otherwise,] Mr. Wood would have stopped breathing and would have gone into a coma were such large doses actually effective." J.A. 220. Wood's execution demonstrated the ceiling effect of midazolam and showed "that the 100 or 500 [milligrams] that might be used in Oklahoma now is not reliably going to be effective to produce the desired effect of a deeply unconscious state that is maintained at a surgical plane of anesthesia." J.A. 230; see also J.A. 176-77.

Notwithstanding midazolam's ceiling effect and the executions of Lockett, McGuire, and Wood, Oklahoma retains its midazolam-based, three-drug protocol. J.A. 158. On January 15, 2015, Oklahoma executed Charles Warner using the same formula used with

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[23] Hydromorphone is a narcotic opioid, sold under the trade name Dilaudid. J.A. 61; J.A. 297.

Lockett, albeit with a higher dose of midazolam. After he was injected with midazolam, but before he was sedated past the point of speech, Warner's last words were reported to have been "my body is on fire." Sean Murphy, *Dying Oklahoma Inmate's Last Words Stir Questions*, Associated Press, Jan. 16, 2015, *available at* http://www.nytimes.com/aponline/2015/01/16/us/ap-us-oklahoma-execution-lawsuit.html. Further information about Warner's execution currently is not available to petitioners, because, in response to discovery requests, Oklahoma has refused to provide evidence about Warner's execution.

II. PROCEDURAL HISTORY

1. On June 25, 2014, petitioners and other death-row prisoners sued respondents under 42 U.S.C. § 1983 in the United States District Court for the Western District of Oklahoma, challenging the State's execution method. Complaint, *Warner*, No. 5:14-cv-665 (June 25, 2014), ECF No. 1. Petitioners amended their complaint on October 31, 2014. Amended Complaint, *Warner*, No. 5:14-cv-665 (Oct. 31, 2014), ECF No. 75. On November 10, 2014, petitioners and then-plaintiff Charles Warner moved for a preliminary injunction to enjoin respondents from carrying out executions in an unconstitutional manner, including through the use of midazolam in a three-drug protocol. Motion for Preliminary Injunction, *Warner*, No. 5:14-cv-665 (Nov. 10, 2014), ECF No. 92.

Following an expedited one-month period for discovery, Scheduling Order re: Preliminary Injunction, *Warner*, No. 5:14-cv-665 (Nov. 6, 2014), ECF No. 88, on December 17-19, the district court held a three-day evidentiary hearing on the preliminary-injunction motion. The court ruled that "parties' experts will be allowed to rebut opposing experts'

reports and otherwise critique each other during their testimony," but the court's schedule did not permit petitioners to present rebuttal witnesses after the State's expert testified. Minute Order, *Warner*, No. 5:14-cv-665 (Dec. 15, 2014), ECF No. 162.

The parties' experts agreed that midazolam has no analgesic (or pain-relieving) qualities, J.A. 204-05, 260-61, and that midazolam is never used as "sole agent for general anesthesia," J.A. 204, 223, 262, 332-33, 340-41; Tr. 661. As described above, the experts diverged on whether 500 milligrams of midazolam would promptly and reliably produce a "deep, comalike unconsciousness" that would render a person insensate to severe pain.

2. On Monday, December 22, the district court ruled from the bench, denying relief.

a. The court found that midazolam has no analgesic properties, that it is not used or approved for anesthesia, and that it is approved for use as a sedative only "*before* administration of other anesthetic agents." J.A. 76 (emphasis added).

The court further found that midazolam increases the risk that a prisoner would feel pain, and that he "will not have the ability to express the fact that he senses pain" during the administration of the second and third drugs. J.A. 79. The court also found that "it is not likely that midazolam would be the [respondents'] first choice." J.A. 86; see also J.A. 79.

Relying solely on respondents' expert's testimony, the district court determined that 500 milligrams of midazolam "would make it a virtual certainty that any individual will be at a sufficient level of unconsciousness to resist the noxious stimuli which could occur from the application of the second and third drugs." J.A. 77. The court asserted, without explana-

tion, that there was "no need to dwell on the fact that [Evans] misplaced a decimal point in one of his observations about the possible lethal effect of midazolam." J.A. 75. The court similarly found persuasive Evans's opinions that the "guaranteed" toxicity of a 500-milligram dose minimized the "risks" of the ceiling effect and paradoxical reaction. J.A. 75, 78. The court found that midazolam had the capacity to cause "*a phenomenon which is not anesthesia* but does have the effect of shutting down respiration and eliminating the individual's awareness of pain." J.A. 78 (emphasis added).

b. The district court construed *Baze* to require petitioners to provide a "known and available" alternative method of execution in order to challenge the use of midazolam here. J.A. 97. Because petitioners failed to show that sodium thiopental was, in fact, commercially available to respondents, the court denied relief. J.A. 99. The court rejected petitioners' argument that, because injecting painful execution drugs after providing a prisoner only with midazolam is inherently a cruel punishment that violates the Eighth Amendment, this aspect of *Baze* is inapplicable. J.A. 89. Instead, it found that *Baze* was "speaking broadly" when it required prisoners to demonstrate an alternative, and that this requirement applies to any Eighth Amendment challenge to any method of execution. J.A. 89-90. Petitioners appealed. Notice of Appeal, *Warner*, No. 5:14-cv-665 (Dec. 23, 2014), ECF No. 176.

3. On January 12, 2015, without hearing argument, the United States Court of Appeals for the Tenth Circuit affirmed the denial of preliminary injunctive relief, adopting wholesale the district court's opinion. J.A. 139. The court of appeals held that the errors in respondents' expert testimony "were not suf-

ficiently serious to render [it] unreliable." J.A. 126; see also 134.

The court of appeals construed *Baze* to require proof of a "demonstrated risk of severe pain," finding it irrelevant that Oklahoma's protocol differs fundamentally from the one in *Baze*. The court of appeals held that *Baze* applies to "all challenges to 'a State's chosen procedure for carrying out a sentence of death.'" J.A. 131. The court of appeals further held that the Tenth Circuit's prior constructions of *Baze* required petitioners to show a known and available alternative to the method of execution at issue to obtain relief. J.A. 129-30 (citing *Pavatt*, 627 F.3d at 1339).

4. On January 13, 2015, petitioners, and Mr. Warner, filed a petition for writ of certiorari along with an application to stay their scheduled executions (No. 14A761). On January 15, 2015, this Court denied the stay application, and Mr. Warner was executed that evening. Justice Sotomayor, joined by Justices Ginsburg, Breyer, and Kagan, dissented from denial of the stay. *Warner*, 135 S. Ct. 824 (Sotomayor, J., dissenting). On January 23, 2015, this Court granted certiorari. On January 28, 2015, this Court granted respondents' application for stays of the then-pending scheduled executions of petitioners. J.A. 140.

SUMMARY OF ARGUMENT

I. The Eighth Amendment prohibits a method of execution that, like Oklahoma's, creates a "substantial risk of serious harm," or an "objectively intolerable risk of harm." *Baze*, 553 U.S. at 50. A protocol using painful lethal drugs is unconstitutional unless the prisoner is first properly administered a drug that reliably ensures a "deep, comalike unconsciousness"

throughout the execution. *Id.* at 44, 53. Midazolam cannot serve that purpose.

A. In *Baze*, there was consensus that sodium thiopental, if properly administered, would produce deep comalike unconsciousness. With midazolam, the opposite is true. Midazolam is not approved for use as the sole anesthetic for painful surgery. Clinical studies showed that midazolam does not reliably induce deep unconsciousness; when used in surgery, patients felt pain. The medical consensus is that midazolam cannot generate deep, comalike unconsciousness. There is also no substantial practice among the states of using midazolam for lethal injections. Although sodium thiopental was widely used for years, only four states have used midazolam in an execution, and only two have tried to use it as anesthesia. On these undisputed facts, the use of midazolam to create deep comalike unconsciousness presents an "objectively intolerable risk of harm." *Baze*, 553 U.S. at 50.

B. Whether a particular method of execution creates a constitutionally unacceptable risk of harm is a question of law subject to de novo review. But the district court's decision to credit the conjecture of respondents' expert that a 500-milligram dose of midazolam would create "a phenomenon that is not anesthesia" was, in any event, clear error. Midazolam's pharmacological properties, including its ceiling effect, mean that it cannot create deep comalike unconsciousness. Relying, as the district court did, on an undocumented "phenomenom" that concededly "is not anesthesia" itself creates an objectively intolerable risk of harm. Respondents' expert supported his opinion with reference only to undisclosed or unreliable sources and mathematical error. His unsupported supposition about how midazolam works in the body and brain has no acceptance within the scientific

community. Although the undisputed facts alone warrant reversal, the district court clearly erred in finding that respondents' expert testimony was reliable. *Anderson* v. *City of Bessemer City, N.C.*, 470 U.S. 564, 573 (1985); *Kumho Tire Co.* v. *Carmichael*, 526 U.S. 137, 149-50 (1999).

II. The Tenth Circuit and other courts have construed *Baze* to set a new and higher standard for obtaining a stay of execution in every Eighth Amendment challenge to a method of execution—one that effectively always forecloses a stay. That contravenes the plurality opinion in *Baze*—which did not cite, much less purport to overrule, the traditional standard for obtaining a stay of execution. *Hill* v. *McDonough*, 547 U.S. 573, 584 (2006) (requiring, *inter alia*, "a significant possibility of success on the merits"); *Barefoot* v. *Estelle*, 463 U.S. 880, 895 (1983) (same). If the Court did intend to create a new and higher stay standard, however, it should clarify that this heightened standard applies only to challenges "on grounds such as those asserted" in *Baze*, where a prisoner challenges a concededly humane method of execution and seeks to "show[] one more step the State could take as a failsafe for other, independently adequate measures." *Baze*, 553 U.S. at 61. Where prisoners do not concede that the State's method, if administered according to plan, would be constitutional, but instead challenge the method itself, then the traditional stay standard applies. *Hill*, 547 U.S. at 584.

III. The Tenth Circuit also erred in dismissing petitioners' claims based on the requirement that petitioners must propose a commercially available alternative drug for their executions. The Eighth Amendment places certain punishments beyond a state's power to carry out, and that prohibition does not van-

ish when a state determines that its preferred alternative is unavailable. The requirement that a prisoner must propose an alternative to avoid a cruel or unusual punishment is foreclosed by this Court's decision in *Hill* v. *McDonough*, 547 U.S. 573, which "unanimously rejected a proposal that . . . suits challenging a method of execution must identify an acceptable alternative." *Jones* v. *Bock*, 549 U.S. 199, 213 (2007) (construing *Hill*, 547 U.S. at 581-82), and which *Baze* did not overrule. The vitality of a core constitutional guarantee does not vary with the marketing decisions or supply constraints of private corporations.

ARGUMENT

I. THE EIGHTH AMENDMENT PROHIBITS EXECUTIONS USING INDISPUTABLY PAINFUL DRUGS UNLESS THEY ARE PRECEDED BY ADMINISTRATION OF A MEDICALLY RELIABLE GENERAL ANESTHETIC.

A. The Undisputed Facts Alone Establish The Objectively Intolerable Risk Of Harm Posed By Using Midazolam As The Sole Anesthetic In An Otherwise Painful Lethal-Injection Protocol.

In *Baze*, this Court grounded its acceptance of a three-drug protocol as a constitutional method of execution on the premise that the first drug in the protocol would "ensure" a "deep, comalike unconsciousness." 553 U.S. at 44. Where that level of unconsciousness is not reliably obtained, the Court recognized that there would be a "constitutionally unacceptable risk of suffocation . . . and pain" from the second and third drugs. *Id.* at 53.

The undisputed evidence here shows that midazolam cannot reliably ensure the "deep, comalike unconsciousness" required where a State intends to cause death with painful drugs. That midazolam has been tested and rejected for use as a sole anesthetic for surgery is sufficient alone to show a "substantial risk of serious harm" and an "objectively intolerable risk of harm" from the second and third drugs, thus establishing that Oklahoma's use of midazolam is "constitutionally unacceptable." *Baze*, 553 U.S. at 50, 53 (quoting *Farmer* v. *Brennan*, 511 U.S. 825, 846 & n.9 (1994)).

First, as in *Baze*, it is uncontested here that without appropriate anesthesia, the second and third drugs in Oklahoma's protocol cause the sort of "barbaric" pain and suffering—suffocation, paralysis, burning—that has always, since the Framing, been prohibited under the Eighth Amendment. See *In re Kemmler*, 136 U.S. 436, 446 (1890) (noting that the Eighth Amendment originally prohibited execution methods that "were manifestly cruel and unusual, [such] as burning at the stake, crucifixion, breaking on the wheel, or the like"). No one disputes that the second drug in Oklahoma's protocol "produce[s] paralysis and a slow death by asphyxiation" resulting in "terror, pain, and needless suffering." Amended Complaint at ¶ 98, *Warner*, No. 5:14-cv-665 (Oct. 31, 2014); Answer to Amended Complaint at ¶ 50, *Warner*, No. 5:14-cv-665 (Nov. 14, 2014), ECF No. 96; J.A. 214-15; J.A. 341; Tr. 351; Tr. 381. Nor does anyone contest that the third drug causes a person to feel "[e]xcruciating, searing, burning" pain. J.A. 215; Amended Complaint at ¶ 99, *Warner*, No. 5:14-cv-665; Answer to Amended Complaint at ¶ 50, *Warner*, No. 5:14-cv-665; J.A. 271; Tr. 353. Thus, the constitutionality of Oklahoma's protocol depends on whether

the first drug can reliably "ensure" a "deep, comalike unconsciousness." *Baze*, 553 U.S. at 44.

Second, the uncontested facts establish that the use of midazolam poses an objectively intolerable risk of severe suffering during the execution. In *Baze*, there was a medical consensus that sodium thiopental produces a "deep, comalike unconsciousness," and if properly administered, will be objectively certain to prevent subsequent pain. See, *e.g.*, 553 U.S. at 44. That consensus reflected the undisputed fact that sodium thiopental can be used as the sole anesthetic agent for otherwise intolerably painful surgery. See DailyMed, *Thiopental Sodium*, Label Archives (Feb. 7, 2011), https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=48745; see also J.A. 296; J.A. 206. It is further undisputed that the dose of sodium thiopental used for lethal injection reliably causes a "barbiturate coma," J.A. 207, where a prisoner could not sense the pain caused by other lethal drugs. See, *e.g.*, J.A. 206-07; J.A. 226.

There is no comparable medical consensus that midazolam is, or can be, reliably used to create a deep comalike unconsciousness. The medical consensus is, in fact, to the contrary. It is undisputed that midazolam is not approved for use, not recommended for use, and is not used, as the sole anesthetic during painful surgery. J.A. 223, 332-33, 341; see also Tr. 143 ("[P]atients who are given midazolam in doses sufficient to produce unconsciousness do not tolerate the noxious stimuli of surgery. We know that from when the drug was being studied and introduced."). All agree that "either in a clinical setting for inducing . . 'deep unconsciousness' or in a lethal-injection setting, midazolam is not the drug of choice." Tr. 689. Even the district court acknowledged that midazolam cannot be relied upon as "anesthesia." J.A. 78.

There also is no consensus among the States regarding midazolam's efficacy for use in capital punishment. Some states that once used or considered using midazolam have already abandoned it. See Brett Barrouquere, *Kentucky Drops 2-Drug Executions, Reworking Method*, Associated Press, Nov. 14, 2014, *available at* http://www.denverpost.com/ci_26937217/kentucky-drops-2-drug-executions-reworking-method; Mark Berman, *Ohio Drops Controversial Lethal Injection Drug, Postpones Upcoming Execution*, Wash. Post, Jan. 9, 2015, *available at* 2015 WLNR 790889. In fact, only four States have ever used midazolam in an execution,[24] and of those, only two—Oklahoma and Florida—have used it as the sole anesthetic for subsequent, painful drugs. J.A. 131-32. *Baze*, 553 U.S. at 53 ("[I]t is difficult to regard a practice as 'objectively intolerable' when it is in fact widely tolerated."); see also *id.* at 42 n.1, 51; *Kennedy* v. *Louisiana*, 554 U.S. 407, 421 (2008) (explaining that application of the Eighth Amendment turns, in part, on "'objective indicia of society's standards, as expressed in legislative enactments and state practice with respect to executions.'" (quoting *Roper* v. *Simmons*, 543 U.S. 551, 563 (2005)). Of the executions in which midazolam was administered, at least three (including Oklahoma's execution of Clayton Lockett) have triggered state investigations into why they did not go as planned. See, *e.g.*, J.A. 376-418; Fernanda Santos & John Schwartz, *A Prolonged Execution in Arizona Leads to a Temporary Halt*, N.Y. Times, July

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[24] *See Warner* v. *Gross*, 135 S. Ct. 824 (2015) (Sotomayor, J., dissenting) (Oklahoma); *Wood* v. *Ryan*, 759 F.3d 1076, 1078 (9th Cir.) (Arizona), *vacated*, 135 S. Ct. 21 (2014); *Chavez* v. *Florida SP Warden*, 742 F.3d 1267, 1270 (11th Cir.) (Florida), *cert. denied sub nom. Chavez* v. *Palmer*, 134 S. Ct. 1156 (2014); *In re Ohio Execution Protocol Litig.*, 994 F. Supp. 2d 906, 909 (S.D. Ohio 2014) (Ohio).

25, 2014, at A15; Alan Johnson, *Capital Punishment; Next Ohio Execution Postponed by Kasich*, Columbus Dispatch, Feb. 8, 2014, at 1B, *available at* http://www.dispatch.com/content/stories/local/2014/02/07/kasich-postpones-march-19-execution.html; cf. *Baze*, 553 U.S. at 46 (noting "no reported problems" in Kentucky's one pre-*Baze* lethal injection).

Together, these undisputed facts are more than sufficient to establish an "objectively intolerable risk" that a prisoner will suffer severe pain if midazolam is used as the sole agent to induce and maintain a deep comalike unconsciousness. If midazolam cannot reliably protect against the pain of surgery, it also cannot reliably protect against the agony of suffocation, paralysis, and "liquid fire." See *Baze*, 553 U.S. at 53 ("[T]here is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride."). On this basis alone, the judgment should be reversed.

B. The District Court Erroneously Credited Unreliable Expert Testimony Regarding Midazolam's Suitability In A Three-Drug Protocol.

Whether a particular method of execution creates an objectively intolerable risk of harm is, ultimately, a legal conclusion involving mixed questions of law and fact, and is therefore subject to de novo review. *Miller* v. *Fenton*, 474 U.S. 104, 116 (1985); *Bose Corp.* v. *Consumers Union of U.S.*, 466 U.S. 485, 510-11 (1984); see J.A. 78. Applying de novo review, the Court should hold that midazolam's pharmacological properties render it incapable of reliably inducing and maintaining deep comalike unconsciousness. But even if the district court's conclusion concerning mid-

azolam is reviewed for clear error, it cannot withstand review.

The district court found that midazolam will reliably create "a phenomenon that is not anesthesia," but that renders a person insensate to pain. J.A. 78. No scientific literature or method supports the district court's finding. For this reason as well, Oklahoma's proposed use of midazolam creates an objectively intolerable risk of harm.

The district court adopted the testimony of the sole expert respondents chose to present. This expert claimed, without scientific support, that the administration of 500 milligrams of midazolam would make it a "virtual certainty" that a prisoner would not feel pain from the administration of the second and third drugs. See J.A. 135 (quoting J.A. 77).

In crediting one expert's unsupported testimony, the district court committed clear error. See *Anderson*, 470 U.S. at 573 (quoting *United States* v. *U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948)) (holding that clear error occurs "when[,] although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed"); see also *United States* v. *Taylor*, 487 U.S. 326, 337 (1988). Courts are charged with "ensur[ing] the reliability and relevancy of expert testimony." *Kumho Tire Co.*, 526 U.S. at 152. "Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." *Daubert* v. *Merrell Dow Pharma., Inc.*, 509 U.S. 579, 590 (1993). As this Court explained in *Kumho,* an expert's reliability may depend on many factors, including "[w]hether a 'theory or technique . . can be (and has been) tested;' [w]hether it 'has been subjected to peer review and publication;' [w]hether, in respect to a particular technique, there

is a high 'known or potential rate of error' . . and [w]hether the theory or technique enjoys 'general acceptance' within a 'relevant scientific community.'" 526 U.S. at 149-50 (quoting *Daubert*, 509 U.S. at 592-94).

This is not a case "where the evidence would support a conclusion either way." *United States* v. *Yellow Cab Co.*, 338 U.S. 338, 342 (1949). Nor is it a case where the district court "analyze[d] the evidence and show[ed] the reasons for the findings." *Id.* at 341; see J.A. 293. Rather, the court credited respondents' expert despite (1) his lack of any authority for his conclusion that a "toxic" dose of midazolam can be extrapolated to determine a dose that will cause a coma; (2) his admitted reliance on non-authoritative sources and mathematical errors in calculating the dose needed to cause death or induce a coma; and (3) his lack of any sources for his beliefs about how midazolam actually works in the human brain. While any one of those defects is reason enough to reject his testimony, respondents' expert's unsupported assumptions and mathematical mistakes, when "viewed in [their] entirety," plainly demonstrate that "a mistake has been committed" by the district court's acceptance of Evans's opinions as fact here. *Anderson*, 470 U.S. at 573-74 (citation omitted).

First, respondents' expert admitted that his crucial testimony that midazolam can cause a coma was based on "extrapolation" and "assumption," Tr. 667-68; he could not provide the sort of authority required for expert testimony to be credible or reliable. See *Kumho*, 526 U.S. at 149-50. Specifically, Dean Evans stated "[t]here's lots of literature to suggest that lower doses of the drug [midazolam] will cause death, so if we're *essentially extrapolating* this piece and *saying there is a linear effect* in terms of administration of

the drug and the concentrations you can receive centrally, then it makes sense, *it's a logical assumption to make in this case*." Tr. 667-68 (emphasis added). But simply "saying there is a linear effect" is not a reliable scientific method, especially when medical literature establishes that there is instead a ceiling effect, and when the expert supplies no authority to the contrary. Evans then built his "extrapolation" upon unsubstantiated anecdotes of deaths caused by unknown dosages of midazolam. Tr. 667-68. Those uncited anecdotes are probative (if at all) only to lethality—and even then, only in ill or elderly persons. See J.A. 217 ("[T]hose type of fatalities occur in 90-year-olds with congestive heart failure who have not had careful titration of the drug. It does not occur in otherwise healthy individuals in that range.").[25] The anecdotes do not address the crucial questions here, such as whether fatal midazolam overdoses are reliably preceded by a sustained comalike state and, if so, how long it takes midazolam to induce such a coma, and how long the victim remains insensate to pain. "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (citations omitted); see *Easley* v. *Cromartie*, 532 U.S. 234, 248 (2001).

Second, Dean Evans's assertion that a 500-milligram dose "absolutely" would ensure a coma, Tr. 661, was based on unreliable sources and an egregious mathematical error. Evans stated that he relied on two sources—the website "drugs.com" and one company's MSDS. Neither source "enjoys 'general acceptance' within a 'relevant scientific community.'" *Kumho*, 526 U.S. at 149-50 (citation omitted).

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[25] Evans failed to mention that what few fatalities involving midazolam exist are "often" reported "in combination with opioids." J.A. 281.

Drugs.com itself warns that it "is not intended for medical advice, diagnosis or treatment." J.A. 276; J.A. 303; see also J.A. 330; J.A. 325. An MSDS is simply an OSHA-mandated document that a company prepares to warn workers of potential dangers posed by the chemicals to which they are exposed. See 29 C.F.R. § 1910.1200(g)(1); Tr. 361—a fact that Evans did not even know, Tr. 656-57. By its own terms, "the information provided [in the MSDS is] without any warranty, express or implied, regarding its correctness." J.A. 279.

The numerical value Dean Evans purportedly derived from these sources also was critically flawed. As to drugs.com, when asked in court to locate the data on that site on which he relied, Evans could not do so. J.A. 330-31. As for the MSDS, Evans cited it for the proposition that a dose of midazolam, at 0.071 mg/kg of body weight, would cause death. J.A. 294; J.A. 327; Tr. 667-68. But Evans later admitted that he miscalculated the MSDS's dosage by a factor of one thousand, which renders Oklahoma's planned 500-milligram dose 10 times less than what, even if the MSDS is treated as a reliable source, would be a "toxic" amount for 70-kilogram person. J.A. 329; Defs.' Ex. 34 at 6558, *Warner*, No. 5:14-cv-665 (Dean Evans's Expert Report).

This remarkable error eliminates the basis for Dean Evans's "logical assumption" that Oklahoma's dosage of midazolam will cause death (much less cause a sustained coma, which is the relevant point). The magnitude of his mathematical error, and the simplicity with which it can be demonstrated, also undermine Evans's reliability as an expert for this subject. The district court stated there was "no need to dwell on the fact that [Evans] misplaced a decimal point in one of his observations about the possible le-

thal effect of midazolam." J.A. 75. That attempt to wish away an erroneous starting point for Evan's "extrapolation" stands alone as clear error, because once the decimal point is correctly placed, the toxicity numbers in the MSDS no longer support Evans's "extrapolation" to the conclusion that the 500-milligram dose of midazolam is necessarily lethal. Cf. *Kumho*, 526 U.S. at 151 ("[I]t will be appropriate for the trial judge to ask, for example, how often an engineering expert's experience-based methodology has produced erroneous results.").[26]

Third, much of Evans's opinions cannot be squared with basic medical facts.[27] For instance, it is a fact that midazolam works by potentiating GABA, allowing GABA to bind to GABA receptors more easily. *E.g.*, J.A. 171-72, 206-07, 232. It is also a fact that administering additional doses of midazolam, as with all benzodiazepines, will eventually lead to a "ceiling effect" once all of the brain's GABA is bound. J.A. 172, 206, 208-09; Tr. 343; Tr. 664; see, *supra* notes 16-17. Evans nonetheless testified that the ceiling effect is limited to the spinal column, and also that "[m]idazolam attaches to GABA receptors, inhibiting GABA." J.A. 311-12. Both points are wrong: the ceiling effect occurs due to the body's finite amount of

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[26] Evans's conclusion is all the more implausible given the executions of Clayton Lockett and Joseph Wood, where the prisoners remained alive despite having received dosages of midazolam that should have, under Evans's theory, put them into a coma and, in fact, killed them. J.A. 392-94; *see also* J.A. 176-77, 213-14, 220, 229-30, 233-34, 349-51; J.A. vol. II 47-48.

[27] Because the truncated schedule did not permit petitioners to call rebuttal witness to address the aspects of Evans's testimony that went beyond his expert report, petitioners provided the Tenth Circuit with an additional declaration and report regarding Evans's testimony. *See* J.A. 235-36; J.A. 283-84.

GABA that is available to bind to GABA receptors, in the brain and elsewhere; moreover, far from *inhibiting* GABA, midazolam *facilitates its binding* to GABA receptors (though it does not itself bind to those receptors in the way barbiturates do). Thus, it is not surprising that Evans could cite no pharmacological or medical literature for his novel, and patently incorrect, assertions. See *Kumho*, 526 U.S. at 149-50. For example, "[t]he spinal cord is not considered by any authoritative publication to be the primary site of anesthetic action, (Perouansky, Pearce & Hemmings, 2015)." J.A. 233.

In sum, the lower court's conclusion that it is a "virtual certainty" that a 500-milligram dose of midazolam will reliably "eliminat[e] an individual's awareness of pain" is based on an expert's unsupported "extrapolation" about a phenomenon other than anesthesia, derived from an incorrectly calculated "lethal" dose of midazolam. J.A. 77-78. That expert's explanation of how midazolam works in the human body was not based on medical authorities and, among other flaws, ignored stark examples of past executions in which high dosages of midazolam failed promptly to induce a coma—executions that instead triggered state investigations as to why the drug did not work as the state had expected. When the record is "viewed in its entirety," Evans's unsupported "extrapolation" makes it "[im]plausible" that his opinion is reliable. *Anderson*, 470 U.S. at 574. For this additional, independent reason, the Court should reverse the decisions below.

II. THE COURT SHOULD CLARIFY THAT PRISONERS ARE ENTITLED TO A STAY UPON A SHOWING OF A SIGNIFICANT POSSIBILITY OF SUCCESS ON THE MERITS.

The Eighth Amendment bars executions that cause "unnecessary cruelty" or a "lingering death." *Baze*, 553 U.S. at 48-49 (quoting *Wilkerson* v. *Utah*, 99 U.S. 130, 136 (1879) and *In re Kemmler*, 136 U.S. 436, 447 (1890)). With regard to cruelty, this Court has emphasized that it is "constitutionally unacceptable" for an execution to impose a "substantial risk of serious harm," or an "objectively intolerable risk of harm." *Baze*, 553 U.S. at 50, 53. Where, along with the other factors supporting a stay,[28] prisoners show "a significant possibility of success on the merits"—*e.g.*, that a method of punishment creates a "constitutionally unacceptable" risk of harm—they should be entitled to a stay of execution. *Hill*, 547 U.S. at 584; *Barefoot*, 463 U.S. at 895-96.

The Tenth Circuit construed *Baze* to set a new and higher standard for obtaining a stay in all Eighth Amendment cases—one that effectively forecloses a stay in all circumstances. Such a construction is at odds with the language and logic of *Baze*. If the Court did indeed intend to state a new and higher standard for a stay, it should clarify that this standard applies only "on grounds such as those asserted" in *Baze*, 553 U.S. at 61, and not to circumstances like those here.

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[28] In addition to a significant possibility of success on the merits, a petitioner seeking injunctive relief must also show that "he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter* v. *Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). These other factors are not at issue—and are met—here.

The challenge in *Baze* arose from the risk of unintentional "maladministration of a concededly humane [execution] protocol." 553 U.S. at 41, 60-61. In explaining the standard for a stay for such a maladministration challenge, the plurality stated that "a *stay* of execution may not be granted *on grounds such as those asserted [t]here* unless the condemned prisoner establishes that the State's lethal-injection protocol creates *a demonstrated risk of severe pain*. [And, h]e must show that the risk is substantial when compared to the known and available alternatives." *Id.* at 61 (emphasis added). The plurality further stated that "[a] State with a lethal injection protocol substantially similar to the protocol we uphold today would not create a risk that meets this standard." *Id.*

The Tenth Circuit took this "demonstrated risk" language out of context in two ways. *First*, the Tenth Circuit misconstrued this language to have replaced the classic stay standard that has long governed Eighth Amendment claims with one that is much more demanding. See J.A. 130 (characterizing the "the demonstration of a risk of severe pain" as the "first requirement for a stay of execution"); see also *Wackerly* v. *Jones*, 398 F. App'x 360, 362 (10th Cir. 2010) ("*Baze* placed its substantive standard at the center of the stay analysis: '*A stay of execution may not be granted . . unless* the condemned prisoner establishes . . *a demonstrated risk of severe pain* . . .' " (citation omitted))

Second, the Tenth Circuit held that this heightened stay standard applies to "*all* challenges to 'a State's chosen procedure for carrying out a sentence of death,'" even where, as here (and unlike in *Baze*), a prisoner contends that the State's method, if carried out as intended, would *not* be humane. J.A. 131 (emphasis added) (quoting *Baze*, 553 U.S. at 48); see J.A.

131 ("*Baze*, as we read [it], w[as] not confined to claims of negligent administration of lethal injection protocols.").

Neither interpretation comports with *Baze*, which did not upset the classic requirements for staying an execution, and which expressly limited its application of those stay requirements to claims "such as those asserted [t]here," *i.e.*, those seeking to improve upon safeguards against the risk of maladministration of a concededly humane protocol. Where, as here, petitioners challenge a drug as inherently unsuited to act as a reliable anesthetic—and therefore challenge Oklahoma's ability to humanely carry out its chosen method of punishment—a petitioner seeking a stay of his objectively intolerable execution need only meet the traditional test for a stay that has always governed preliminary injunctions, *i.e.*, "a significant possibility of success on the merits," *Hill*, 547 U.S. at 584.

1. *Baze*'s use of the phrase "demonstrated risk" does not necessarily displace this Court's traditional standard for obtaining a stay of execution—*viz.*, "a significant possibility of success on the merits" and, *inter alia*, a likelihood of irreparable injury. *Hill*, 547 U.S. at 584. Demonstrating a likelihood of being able to show an objectively intolerable risk of pain is what one ordinarily would expect a prisoner to do to obtain a stay. None of the opinions in *Baze* cited *Barefoot* v. *Estelle*, 463 U.S. 880, the seminal case laying out the standard for a stay of execution, or *Hill* v. *McDonough*, 547 U.S. at 584, a more recent challenge to a lethal-injection protocol that resulted in a unanimous decision and a reaffirmation of *Barefoot*'s standard in method-of-execution challenges. The absence of any discussion in *Baze* about "the familiar standard for securing a stay" in a capital case, *Gray*

v. *Kelly*, 131 S. Ct. 2956, 2957 (2011) (referring to *Barefoot*), is a further indication that *Baze* did not alter the stay standard reaffirmed so recently in *Hill*. See *Shalala* v. *Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 18 (2000) ("This Court does not normally overturn, or so dramatically limit, earlier authority *sub silentio*.").

The unique claim in *Baze* confirms that *Baze* left the classic stay standard intact. In *Baze*, petitioners challenged a settled "method of execution believed to be the most humane" currently used. *Baze*, 553 U.S. at 53, 62; see also *id.* at 44 (noting 30 of 36 States "use[d] the same combination of three drugs"). If Kentucky's method was carried out correctly, petitioners conceded, it was certain that the method "will result in a painless death." *Id.* at 62. All agreed that the challenged method was chosen with an "earnest desire to provide for a progressively more humane manner of death" as compared to past methods. *Id.* at 51; see *id.* at 43 n.1 ("[T]he States were motivated by a desire to find a more humane alternative to then-existing methods."). There was no substantial evidence or scientific data supporting "a better method." *Id.* at 57.

The petitioners in *Baze* urged the adoption of an "untested alternative," one that petitioners "concede[d] ha[d] not been adopted by any State and ha[d] never been tried." *Id.* at 41, 51-52. Moreover, the risks they sought to avoid had never transpired—"extensive" factual proceedings failed to reveal even one "isolated mishap" or "reported problem[]" that had occurred in Kentucky using the challenged method. *Id.* at 46, 50.

That Eighth Amendment challenge was thus unlike any other the Court had previously confronted. In all prior method-of-execution cases, the allegation was

that the method itself—if carried out as intended—would inflict needless pain in violation of the Eighth Amendment. *E.g.*, *Louisiana ex rel. Francis* v. *Resweber*, 329 U.S. 459, 464 (1947); *Kemmler*, 136 U.S. at 443-44; *Wilkerson* v. *Utah*, 99 U.S. 130, 136 (1878). In *Baze*, however, no one challenged the propriety of the lethal-injection formula if properly administered. In fact, all agreed that science had progressed such that, barring human error in the administration of the drugs, it was certain that Kentucky's protocol could and would result in "a painless death." *Baze*, 553 U.S. at 62. It was assumed that, in the future, executions would become only "progressively more humane." *Id.* at 51, 62.

Given the expectation of steady "progress toward more humane methods of execution," *id.* at 62, the Court recognized that it "would serve no meaningful purpose" to wade into further constitutional challenges "on grounds *such as those asserted* [*t*]*here*," which sought to impose a "failsafe for other, independently adequate measures," unless a prisoner could show a "demonstrated risk of severe pain," *id.* at 61. Without such a concrete "demonstrat[ion]," it is hard to see how a prisoner challenging "a lethal injection protocol *substantially similar* to the protocol . uph[e]ld" in *Baze* could ever show a significant possibility of success on a claim seeking to upset a constitutionally satisfactory protocol. *Id.* The *Baze* plurality's requirement of a "demonstrated risk" would thus appear to be a shorthand way of describing the hurdle that prisoners would need to overcome to show a significant possibility of success on a *Baze*-type claim.

2. Even if *Baze* established a new and uniquely restrictive stay standard, the Court should clarify that this standard applies only to challenges akin to that in *Baze*, and unlike the challenge here. The

Tenth Circuit concluded that *Baze*'s requirement of a "demonstrated risk" applied to "*all* challenges to 'a State's chosen procedure for carrying out a sentence of death.'" J.A. 131 (emphasis added) (quoting *Baze*, 553 U.S. at 48). Whether or not the plurality intended for the "demonstrated risk" language to supplant the classic stay standard, the *Baze* plurality made clear that its reasoning applied only to claims based on "on grounds such as those asserted [t]here," which sought merely a "failsafe for other, independently adequate measures" to a concededly humane drug formula.

Key factors that distinguished the *Baze* challenge are absent here. Oklahoma's new protocol is neither "more humane" than its predecessors, nor supported by a consensus regarding its efficacy or reliability. *Baze*, 553 U.S. at 51; see *id.* at 43 n.1. Oklahoma turned to midazolam as a replacement for pentobarbital without a basis in science. Cf. *id.* at 42; J.A. 327. Instead, the Department of Corrections responded to political pressure to avoid having to delay any executions, J.A. 147, 148, and relied on reports from other States and internet postings from "Wiki leaks or whatever it is," J.A. vol. II 7. Lacking a scientific consensus for Oklahoma's intended purpose, midazolam has been uniformly rejected as a single anesthetic agent for painful procedures *outside* of the capital context, J.A. 206; J.A. 223; J.A. 332-33; Tr. 145, and has only rarely (and not without incident) been used in three-drug lethal-injection protocols.

Most importantly, petitioners claim that Oklahoma's method of execution, even if carried out as written, is unconstitutional. Petitioners contend that midazolam is inherently incapable of reliably creating deep, comalike unconsciousness. That challenge goes to the method of execution and assumes that Oklahoma will carry out its protocol as written. In that

crucial respect, this challenge is fundamentally different than that in *Baze*, where petitioners "simply" were proposing "one more step the State could take as a failsafe for other, independently adequate measures." *Baze*, 553 U.S. at 60-61.

Given these sharp departures from *Baze*, it makes little sense to require petitioners here to show a "demonstrated risk" in the highly restrictive sense that the Tenth Circuit and other courts have interpreted that term, *i.e.*, as requiring proof that the exact same method has produced unconstitutional results in the past. *E.g.*, *Lopez* v. *Brewer*, 680 F.3d 1084, 1090 (9th Cir. 2012) (Berzon, J., concurring in part and dissenting in part from denial of stay of execution) (agreeing that prisoner could not "demonstrate" enough to meet "the high standard" set by *Baze*, and noting that, while prisoners could meet this burden by "demonstrat[ing] that past executions carried out in accord with similar procedures have resulted in executions that violated the Eighth Amendment," such a showing is made "impossible" by repeated changes to a state's protocol).

Clarification as to the stay standard is especially important to ensure that a prisoner has an opportunity to obtain review of a novel execution method, rather than (as in *Baze*) a method that long experience has shown *not* to create an objectively intolerable risk of pain. Were a state to attempt to use some other mild sedative in place of an anesthetic, for example, it should not be able to defeat a prisoner's request to stay his execution simply by saying that because it is the first State to try this particular combination, no objectively intolerable risk can possibly be "demonstrated." A series of exceptionally painful executions is surely one way to demonstrate an intolerable risk, but it cannot be the only way. A stay should

be available if and when a prisoner can show a substantial likelihood of success in proving an Eighth Amendment violation, including by showing that the drugs a state plans to use present a substantial or objectively intolerable risk of imposing severe pain.

III. CONDEMNED PRISONERS NEED NOT PLEAD ALTERNATIVES TO AVOID AN UNCONSTITUTIONALLY CRUEL EXECUTION.

There has long been agreement that the Eighth Amendment places certain means of execution beyond the government's power. The government cannot burn a prisoner at the stake, for instance, nor starve him to death, nor kill him through cruel means resembling torture. See *Baze*, 553 U.S. at 98-99 (Thomas, J., concurring in judgment); *Kemmler*, 136 U.S. at 44; *Wilkerson*, 99 U.S. at 136 (1879) ("[I]t is safe to affirm that punishments of torture . . are forbidden . . . ."). *Baze* established that the administration of a paralytic and potassium chloride to a conscious person would amount to just such an objectively intolerable infliction of pain. There is no difference, from a constitutional perspective, between the sensation of burning and torturous suffocation caused by lethal chemicals or a pyre. In either instance, the Constitution forbids the State from carrying out such an execution, without exception.

The courts below, however, misread *Baze* to hold that an otherwise unconstitutional execution nonetheless may go forward if the condemned prisoner is unable or unwilling to propose a readily available, constitutionally viable means of executing himself. For a petitioner to meet this unprecedented burden, the courts below required that any proposed alternative drug be commercially purchasable by states on the open market. See J.A. 127, 130; J.A. 99 ("[A]n al-

ternative drug that its manufacturer or its distributor or the FDA will not allow to be used for lethal injection purposes is no drug at all for *Baze* purposes." (quoting *Chavez* v. *Florida SP Warden*, 742 F.3d 1267, 1275 (11th Cir.), *cert. denied sub nom. Chavez* v. *Palmer*, 134 S. Ct. 1156 (2014))). On that basis, sodium thiopental and pentobarbital were found to be "not available to the DOC." J.A. 127 ("[S]odium thiopental is now effectively unobtainable anywhere in the United States."); Tr. 296 ("[T]he [State's] vendor . . . didn't want to sell [Oklahoma] pentobarbital any longer."). Affirming that sodium thiopental and pentobarbital drugs are "unavailable" (an assertion undermined by subsequent executions using pentobarbital),[29] the Tenth Circuit held that petitioners' otherwise objectively intolerable executions could proceed. J.A. 127, 130.

That cannot be—and is not—the law. A rule that permits a cruel execution to go forward for immediate lack of a humane alternative runs contrary to controlling precedent, misapplies *Baze*, and cannot be

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[29] Texas, Georgia, and Missouri collectively have carried out six executions using pentobarbital since the petition for certiorari was filed in this case, *see Execution List 2015*, Death Penalty Information Center, http://www.deathpenaltyinfo.org/execution-list-2015 (last visited Mar. 5, 2015), and at least four states—Georgia, Mississippi, Missouri, and Texas—have used or plan to use pentobarbital from compounding pharmacies, *see* Wendy N. Davis, *Compound Sentence: States Keep Mum On Where Lethal Injection Drugs Are Made*, 100-MAR A.B.A. J. 15 (2014); Denise Grady, *Three-Drug Protocol Persists for Lethal Injections, Despite Ease of Using One*, N.Y. Times, May 2, 2014, at A16; *Texas: State Bought Execution Drugs From a Compounding Pharmacy*, N.Y. Times, Oct. 3, 2013, at A21. Oklahoma has not explained why pentobarbital is available to other states but not to Oklahoma.

squared with this Court's constitutional jurisprudence.

1. The Tenth Circuit faulted petitioners for challenging the constitutionality of midazolam without offering a "known and available alternative" to use in its place. J.A. 130. Petitioners clearly pleaded that they are not challenging the constitutionality of lethal injection per se, but seek only to prevent Oklahoma from using this specific combination of drugs. Amended Complaint at ¶ 24, *Warner*, No. 5:14-cv-665 (Oct. 31, 2014). Nevertheless, the Tenth Circuit held that petitioners' failure to plead a readily and commercially available alternative to midazolam independently defeated petitioners' Eighth Amendment claim. See J.A. 130 (citing *In re Lombardi*, 741 F.3d at 895-96 ("Without a plausible allegation of a feasible and more humane alternative method of execution, . . . plaintiffs have not stated an Eighth Amendment claim . . "), *cert. denied sub nom. Zink* v. *Lombardi*, 134 S. Ct. 1790 (2014))).

That holding contravenes *Hill* v. *McDonough*, 547 U.S. 573 (2006), which "unanimously rejected a proposal that . . . suits challenging a method of execution must identify an acceptable alternative." *Jones*, 549 U.S. at 213 (construing *Hill*, 547 U.S. at 581-82). In *Hill*, a prisoner claimed that a state's protocol for administering the first drug in its three-drug protocol risked failing "to render painless the administration of the second and third drugs." 547 U.S. at 578. Hill did not propose an alternative method to use for his execution, though he did concede that, in the abstract, "other methods of lethal injection the Department could choose to use would be constitutional." *Id.* at 580. Reasoning that Hill's claim would, if successful, temporarily prevent the State from executing him, the district court concluded that Hill's suit

amounted to a successive (and impermissible) petition for a writ of habeas corpus attacking his death sentence. *Id.* The U.S. Court of Appeals for the Eleventh Circuit affirmed.

Before this Court, the United States as *amicus curiae* urged that method-of-execution claims should proceed only if "the prisoner identifies an alternative, authorized method of execution." *Id.* at 582. "A suit like Hill's that fails to do so, the United States maintain[ed], is more like a claim challenging the imposition of any method of execution—which is to say, the execution itself—because it shows the complainant is unable or unwilling to concede acceptable alternatives [e]xcept in the abstract." *Id.* (quotations omitted).

The Court unanimously rejected the United States' proposal as imposing "heightened pleading requirements" inconsistent with the Federal Rules of Civil Procedure and the Constitution. *Id.* Instead, the Court concluded that "the traditional pleading requirements" for 42 U.S.C. § 1983 actions raising an Eighth Amendment claim do not include a requirement that a capital litigant propose an alternative method of execution. *Id.* Thus, Hill's underlying contentions about the risks of pain posed by Florida's lethal-injection protocol, without more, stated a claim for relief. *Id.* Petitioners' contentions about the objectively intolerable risks that Oklahoma's method of execution presents are equally sufficient to state a claim for relief, without the necessity of proposing an alternative method. This Court should reaffirm *Hill* and reject the Tenth Circuit's requirement on that ground alone.

2. The Tenth Circuit's "alternative method" requirement also finds little support in *Baze* or this Court's other decisions.

a. *Baze*'s plurality opinion states that a petitioner "must show that the risk [complained of] is substantial *when compared to the known and available alternatives.*" *Baze*, 553 U.S. at 61 (emphasis added). But that statement does not purport to add a new element to Eighth Amendment claims, and had nothing to do with commercial availability. Instead, as discussed above, *Baze* addressed an attempt to compel States to improve upon a settled, concededly humane method of execution. 553 U.S. at 61 (pronouncing stay standard for "grounds such as those asserted [t]here"). The evaluation of alternatives in *Baze* was inescapable, as the point of the challenge was to impose a particular alternative method on the State. The Court concluded that any such alternative, to be constitutionally mandated, would have to be "significantly" more humane than the existing protocol, "feasible"—*i.e.*, more science than fiction—and "readily implemented"—*i.e.*, not prohibitively difficult. *Baze*, 553 U.S. at 52; see *id.* at 62 ("[T]he alternative that petitioners belatedly propose has problems of its own, and has never been tried by a single State."). In short, *Baze* presupposes that the condemned prisoner seeks to force the State to adopt a substantially improved method in lieu of its concededly constitutional method. Given this premise of *Baze*, it is essential that the prisoner's alternative be known and available. If not, a court's imposition of an unavailable alternative would result, de facto, in the State's inability to carry out the capital sentence using its available and constitutional method of execution.

The premise of this challenge is different. Here, the State's proposed method of execution is inherently and unconstitutionally cruel. In that circumstance, a petitioner need not provide the State with a constitutional alternative. See *Baze*, 553 U.S. at 101-02

(Thomas, J., concurring in the judgment) ("It strains credulity to suggest that the defining characteristic of burning at the stake, disemboweling, drawing and quartering, beheading, and the like was that they involved risks of pain that could be eliminated by using alternative methods."); *Warner*, 135 S. Ct. at 826 (Sotomayor, J., dissenting) ("[I]t would be odd if the constitutionality of being burned alive, for example, turned on a challenger's ability to point to an available guillotine."). The cruelty of a punishment is all that petitioners need to establish to prevail.

b. Petitioners' view of *Baze* is supported by the absence of any reference in *Baze* to *Hill* or to a subsequent case rearticulating *Hill*'s holding. See *Jones*, 549 U.S. at 213 ("[*Hill*] unanimously rejected a proposal that . . . suits challenging a method of execution must identify an acceptable alternative.") Had the Court intended to "dramatically limit [*Hill*'s] authority," it would not have done so "*sub silentio*." *Shalala*, 529 U.S. at 18.

c. The Tenth Circuit's requirement also finds no support in other Eighth Amendment decisions. In *Miller* v. *Alabama*, 132 S. Ct. 2455, 2475 (2012), the Court held unconstitutional a juvenile's life-without-parole sentence, but did not require the petitioner to establish (nor did the Court dictate) an alternative prison term. See *Graham* v. *Florida*, 560 U.S. 48, 82 (2010) (same); *Solem* v. *Helm*, 463 U.S. 277, 303 (1983) (same, for non-violent felony). Likewise, in holding that "the Eighth Amendment forbids Congress to punish [wartime desertion] by taking away citizenship," the Court neither discussed nor required the petitioner to propose the contours of what would constitute an appropriate alternative punishment. *Trop* v. *Dulles*, 356 U.S. 86, 103 (1958) (plurality opinion). And in *Weems* v. *United States*, 217 U.S.

349, 382 (1910), the Court held unconstitutional a sentence of 12 years at hard labor in irons for falsifying public records, and vacated the sentence rather than requiring petitioner to propose a less-cruel alternative punishment.

3. It also would be unprecedented to allow the protection of a core constitutional guarantee to turn on the decisions of private corporations who may, or may not, choose or be able to supply products to U.S. prisons. If that were the rule, then purely by dint of economic, regulatory, or marketing conditions, the risks posed by midazolam could be constitutionally intolerable one week and perfectly acceptable the next. The Eighth Amendment's protection against cruelty cannot fluctuate depending on market forces or supply-line interruptions. See *Home Bldg. & Loan Ass'n* v. *Blaisdell*, 290 U.S. 398, 425 (1934) ("Emergency does not increase granted power or remove or diminish the restrictions imposed upon power granted or reserved."); *Ex parte Milligan*, 71 U.S. 2, 120 (1866) (rejecting argument that "necessity" permitted abrogation of the right to trial by jury, and reasoning that "[n]o doctrine, involving more pernicious consequences, was ever invented by the wit of man than that any of [the Constitution's] provisions can be suspended during any of the great exigencies of government"). Such a mutable standard is incompatible with the Constitution's fundamental guarantees of liberty, including freedom from cruel and unusual punishment.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be reversed.

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